ADMINISTRATIVE and CLINICAL EDITS **July 25, 2003**

Clinical edits are designed to enhance patient care and optimize the use of program funds through therapeutically prudent use of pharmaceuticals. Point-of-service pharmacy claims will be routed through an automated computer system to apply edits specifically designed to assure effective drug utilization. The edits are based on evidence-based clinical criteria and available nationally recognized peer-reviewed information. Through the clinical edit process therapy will automatically and transparently be approved for those patients who meet any of the system approval criteria. For those patients who do not meet the system approval criteria, therapy will require a call to the Medicaid Drug Prior Authorization hotline at (800) 392-8030 to initiate a review and potentially authorize claims.

The following medications are currently processed through a clinical edit:

2nd GENERATION ANTIHISTAMINES: Effective for dispensing dates beginning February 26, 2003, this category of drug products will be processed through a clinical edit, step therapy. The primary edit criteria includes the following:

- Reference Drug – Loratidine
- Patients currently receiving an agent within the therapeutic class and compliant with therapy*
  *Compliance is defined as utilization for 60 days out of 90 days of concurrent therapy
- Documented adverse drug event to reference drug
- Documented therapeutic failure with reference drug
- Documented adequate trial period

ACE INHIBITORS: Effective for dispensing dates beginning March 12,2003, this category of drug products will be processed through a clinical edit, step therapy. The primary edit criteria includes the following:

- Reference Drug(s) – Lisinopril and Captopril
- Patients currently receiving an agent within the therapeutic class and compliant with therapy*
  *Compliance is defined as utilization for 60 days out of 90 days of concurrent therapy
- Documented adverse drug event to reference drug
- Documented therapeutic failure with reference drug
- Documented adequate trial period

ALINIA ORAL SUSPENSION (NITAZOXANIDE): Effective for dispensing dates beginning May 14, 2003, this drug product will be processed through a clinical edit. The primary clinical edit criteria includes the following:

- Patient is between the age of 1 year and 11 years.
- Diagnosis of Giardiosis or Cryptosporidiosis.

ACTIQ: Effective for dispensing dates beginning March 26, 2003, this drug product will be processed through a clinical edit. The primary edit criteria includes the following:

- Diagnosis of Cancer
- Appropriate initial therapy titration
- Claims for patients 18 years of age and under subject to clinical review
- Current dose optimization limitations
  - Max 4 units per day

CIPRO XR: Effective for dispensing dates beginning Feb 17, 2003, this drug product will be processed through a clinical edit. The primary edit criteria includes the following:

- ♦ Diagnosis of acute uncomplicated urinary tract infection
- ♦ Therapy limitation – 3 days

COX-2 INHIBITORS: Effective for dispensing dates beginning December 16, 2002, this category of drug products are processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Familial adenomatous polyposis in the last 2 years (Celecoxib only)
- ♦ GI toxicity risk factors
  - Age 65 or above
  - Pud or GI bleed
  - Warfarin use in the most recent 45 days
  - Corticosteroid use in the most recent 90 days
  - High dose NSAID use in the last 45 days
- ♦ Rheumatoid or osteoarthritis
- ♦ NSAID therapeutic failure

DIENESTROL POWDER: Effective for dispensing dates beginning November 18, 2002, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Female
- ♦ Diagnosis of:
  - Atrophic vaginitis
  - Kraurosis vulvae
  - Associated postmenopausal vaginal atrophy
- ♦ Use as a compound drug

DURAGESIC: Effective for dispensing dates beginning May 14, 2003, this drug product will be processed through a clinical edit. The primary edit criteria includes the following:

- ♦ Appropriate diagnosis – Cancer, Chronic Non-Malignant Pain
  - Subject to clinical review
- ♦ Appropriate initial therapy titration
- ♦ Claims for patients 18 years of age and under subject to clinical review
- ♦ Dose Optimization limitations
  - Doses >300mcg per hour

EMEND: Effective for dispensing dates beginning May 26, 2003, this drug product will be processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Diagnosis of cancer
- ♦ Dispense quantity of 3 tablets

FORTEO: Effective for dispensing dates beginning January 27, 2003, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Diagnosis of Osteoporosis
- ♦ Trial/failure or intolerance on Bone Reabsorption Inhibitors

GEODON INJECTABLE: Effective for dispensing dates beginning October 25, 2002, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- Diagnosis of Schizophrenia
- Prescribing physician is a Psychiatrist
- Emergency Room use will not be impacted by this program

H2 ANTAGONISTS: Effective for dispensing dates beginning June 18, 2003, this category of drug products will be processed through a clinical edit, step therapy. The primary edit criteria includes the following:

- **Reference Drug – Ranitidine**
  - Excluding ranitidine caps, Zantac Granules®, and Zantac Effervescent Tabs®
- Patients currently receiving an agent within the therapeutic class and compliant with therapy
  - Compliance is defined as utilization for 60 days out of 90 days of concurrent therapy
- Documented adverse drug event to reference drug
- Documented therapeutic failure with reference drug
- Documented adequate trial period on reference drug

HMG CoA REDUCTASE INHIBITORS: Effective for dispensing dates beginning February 18, 2003, this category of drug products are processed through a clinical edit, step therapy. The primary edit criteria includes the following:

- Reference Drug – Lovastatin
- Patients currently receiving an agent within the therapeutic class and compliant with therapy*

  *Compliance is defined as utilization for 60 days out of 90 days of concurrent therapy
- Documented adverse drug event to reference drug
- Documented therapeutic failure with reference drug
- Documented adequate trial period

HYDROXYPROGESTERONE CAPROATE POWDER: Effective for dispensing dates beginning November 18, 2002, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- Female
- Diagnosis of:
  - Amenorrhea (primary or secondary)
  - Dysfunctional uterine bleeding
  - Metrorrhagia
  - Production of secretory endometrium
  - Shedding of epidermal uterine layer
- Use as a compound ingredient

OXANDRIN 10mg Tablets: Effective for dispensing dates beginning November 25, 2002, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- Therapy to offset protein catabolism associated with prolonged administration of corticosteriods
- Treatment of bone pain frequently accompanying osteoporosis
- Therapy to promote weight gain following extensive surgery, chronic infection, or severe trauma

ORAL BUPRENORPHINE (SUBUTEX, SUBOXONE): Effective for dispensing dates beginning May 14, 2003, this drug product will be processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Diagnosis of Opioid Drug Dependency
- ♦ Clinical Pharmacist review to determine if the prescriber possesses a Substance Abuse and Mental Health Services Administration waiver.

OXYCONTIN: Effective for dispensing dates beginning May 28, 2003, this drug product will be processed through a clinical edit. The primary edit criteria includes the following:

- ♦ Appropriate diagnosis – Cancer, Chronic Non-Malignant Pain
  -Subject to clinical review
- ♦ Claims for patients 18 years of age and under subject to clinical review
- ♦ Appropriate initial therapy titration
- ♦ Current dose optimization limitations
  - 10mg, 20mg, 40mg – maximum of 8 tablets per day
  - 80mg – maximum of 12 tablets per day

STRATTERA: Effective for dispensing dates beginning February 10, 2003, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Diagnosis of ADHD
- ♦ If patient is 23 years of age or older require documentation of goals of therapy

SYNAGIS (PALIVIZUMAB): Effective for dispensing dates beginning May 14, 2003, this drug product will be processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Treatment is being administered at the start or within the RSV season (based on geographical area).
- ♦ < 2 years old with chronic lung disease that required treatment in the past 6 months.
- ♦ Patients born $\leq$29 weeks of gestation and are currently $\leq$1 year of age.
- ♦ Patients born between 29 and 32 weeks gestation and are currently $\leq$6 months of age.

Patients born between 32 and 35 weeks gestation and are currently $\leq$6 months of age if they have an multiple risk factors present such as: congenital heart defects (acyanotic), neurological disease, low birth weight, more than 1 young siblings, child care center attendance, exposure to tobacco smoke, anticipated cardiac surgery, and/or long distance from hospital care.

THALOMID: Effective for dispensing dates beginning May 5, 2003, this drug product will be processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Diagnosis of cancer or,
- ♦ Diagnosis of leprosy

VFEND: Effective for dispensing dates beginning September 25, 2002, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- ♦ Diagnosis of:
  - Acute invasive aspergillosis

- Serious fungal infections
- Invasive mycoses

ZELNORM: Effective for dispensing dates beginning August 7, 2002, this drug product is processed through a clinical edit. The primary clinical edit criteria includes the following:

- Female
- Diagnosis of irritable bowel syndrome
- Constipation is primary bowel symptom

ZETIA: Effective for dispensing dates beginning December 30, 2002, this drug product is being processed through a clinical edit. The clinical edit criteria includes the following:

- Diagnosis of hyperlipidemia/hypercholesterolemia
- Documented trial/failure on a HMG Co A Reductase Inhibitor within the last 45 days
- Documented adverse drug reaction to a HMG Co A Reductase Inhibitor

**** Please note these edits are fluid and this document will be updated frequently.***